THE NATIONAL CHILDREN'S STUDY

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and the

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NICHD, CDC, NIEHS

U.S. Environmental Protection Agency

Brief History

- ***The President's Task Force on Health Risks and Safety Risks to Children (1998-present)***
- ***Children's Health Act of 2000 (PL 106-310)***
  - Authorized the Director of NICHD, together with representatives from EPA, CDC, and (later) NIEHS
  - To plan and implement a national longitudinal study of environmental influences on children's health and development
    - Environment defined broadly to include physical, chemical, biological, and psychosocial factors
  - To investigate basic mechanisms of developmental disorders and environmental factors, both risky and protective

Study Concepts

- High quality longitudinal study of children, their families and their environment - ~100,000 from before birth to adulthood
- National in scope
- Environment defined broadly (chemical, physical, behavioral, social, cultural)
- Study common range of “environmental” exposures and less common outcomes
- Environment & genetic expression
- State-of-the-art technology – tracking, measurement, data management
- National resource for future studies

Who It's All About!

Priority Outcomes and Exposures

- Priority health and disease outcomes
  - Pregnancy outcomes
  - Neurodevelopment and behavior
  - Childhood injury
  - Asthma
  - Obesity and physical development
- Priority environmental exposures and other factors
  - Physical environment
  - Chemical exposures
  - Biological environment
  - Psychosocial exposures
  - Genetics

The NCS and Environmental Health Risk Assessment

Will address important issues, such as -

- Ranges and types of exposures throughout development
- Role of environmental factors in children's health
- Contribution of exposure to burden of disease in children
- Long-term health effects from early exposures of children and their parents

  asthma, cancer, cardiovascular disease, obesity, diabetes, neurologic conditions

The NCS and Environmental Health Risk Assessment

- Factors that alter susceptibility to environmental agents, e.g.,
  - Specific genetic polymorphisms and susceptibility to pesticides
  - Immune deficiencies and increased risk of asthma
  - Early allergen exposures and enhanced immune function (hygiene hypothesis)
- Disparities in health outcomes due to . .
  - race, ethnicity, poverty, housing, income, nutrition, near heavy industry or toxic waste sites, etc
- Responses to environmental exposures that vary by age or life stage
- Effects of aggregate exposures to a chemical or cumulative exposures to mixtures

The NCS and Environmental Health Risk Assessment

- Are default risk assessment approaches sufficient to protect children? For example . .
  - How much higher, or lower, are exposures in children versus adults?
  - Do the types of effects (transient versus irreversible) vary by life stage?
  - Is a 10-fold uncertainty factor sufficient to account for variability in response, particularly to protect children?
  - When and how are children at greater risk of exposure than adults?

Projected Time Line

2000-2004	Pilot study/methods development work
2001-2002	Form advisory committee and working groups
Periodically:	Meetings, peer reviews, consultations
2003-2004	Finalize specific hypotheses, develop study design
Late 2005	Select initial centers or alternatives and pilot test core protocol
Mid 2006	Begin full study with vanguard centers
2005-2007	Enroll additional centers
2009-2010	First preliminary results available from pregnancy
2007-2030	Analyze data as collection continues, publish results throughout

Protocol Development

- Who, what, when, where and . . . later, how
- Sample design
  - Selection of geographic locations and individual participants
- Timing of recruitment
  - Preconception
  - Early in pregnancy (<4 weeks)
  - Later in pregnancy

Recent Workshops

Assessing Incidence and Outcomes of Mild Traumatic Brain Injury	September 11-12, 2003
Placental Measurements	November 3-4, 2003
Psychosocial Stress and Pregnancy and the Infant	November 12-13, 2003
Physical Activity	November 17-18, 2003
Herbals and Dietary Supplements	December 16, 2003
Effects of Media	January 22–23, 2004
Impact of Rurality	March 2, 2004
Sampling Design	March 21-22, 2004

Recent/Upcoming Workshops

Day-Specific Probabilities of Pregnancy	May 17-18, 2004
Possible Roles for Inclusion of the Study of Cancer in the NCS	May 20, 2004
Measurement of Maternal and Fetal Infection and Inflammation	May 20-21, 2004
Questionnaire and Diary-Based Methods for the Early Assessment of Asthma-Related Health Outcomes	May 27, 2004
Gene-Environment Interaction and the Regulation of Behavior	June 2-3, 2004

Current Methods Development & Pilot Studies

- Development of low-cost, low-burden methods and alternative exposure measurement (validation) designs
- Methods for newborn assessment
- Utility of frozen breast milk to assess environmental toxicants for metabolic, nutritional, and genomic endpoints
- Feasibility of using 3D ultrasound for fetal assessment
- Methods of eliciting community involvement, subject recruitment and retention
- Lessons learned from the EPA/NIEHS children's environmental health centers

Current Methods Development & Pilot Studies

- Measures to evaluate health status, emotional and social functioning, and mental development and cognition
- Measuring housing quality and characteristics
- Assessing dietary intakes and patterns in women and young children: methodological issues
- Evaluation of disposable diapers for quantitative measurements of pesticide metabolites in urine samples
- Measurement and analysis of exposures to environmental pollutants and biological agents

Current Status of Infrastructure and Support

- In place
  - Scientific support: reviews, analyses, surveys (NIH and EPA contracts)
  - Information technology development
- Anticipated procurements over next year
  - Clinical/data coordinating center
  - Biological/environmental sample repository
  - Initial study sites (vanguard sites)
  - Laboratory services

Funding Status

- PLANNING (FY00-03)
  - $20.7 million (from existing HHS & EPA budgets)
- START-UP (FY04-05)
  - ~$12 million available in FY04
  - $26 million estimated need, $12 million total in President's FY05 Budget
- IMPLEMENTATION (FY05-29)
  - Total estimated cost: $2.7 billion over 24 years

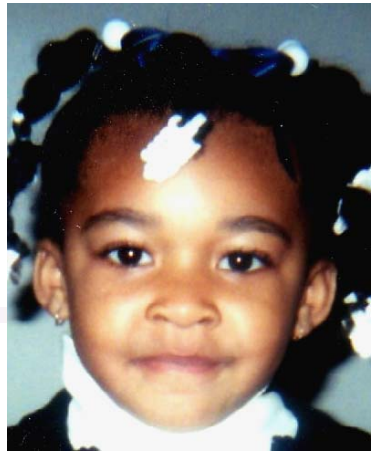
Approximate Annual Cost to U.S. from Disease Burden

	Estimated Annual Cost – All Ages	Estimated Number of Children Affected in US
Injury	$224 billion	10.8 million
Diabetes	$ 132 billion	206,000
Obesity	$117 billion	9 million
Asthma	$ 14 billion	9 million
Autism	$7.6 billion	93,000
Schizophrenia	$65.2 billion	2.2 million (adult onset)

Contact Information

- Check the Web site: http://NationalChildrensStudy.gov
- Join the listserv for news and communication
- Contact us at ncs@mail.nih.gov

Contacts



- EPA members of the Interagency Coordinating Committee
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